

Cancer Detection Programs: Every Woman Counts

PROGRAM MANUAL FOR PRIMARY CARE PROVIDERS



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1 SECTION ONE: INTRODUCTION TO THE CLINICIAN MANUAL

Welcome to Cancer Detection Programs: Every Woman Counts. This Program is designed to provide breast and cervical cancer public education and outreach, screening, follow-up diagnostic services, case management, and rescreening for low income uninsured or underinsured women in California. The Cancer Detection Section (CDS) manages the multi-faceted Program and is a part of the California Department of Health Services' Chronic Disease and Injury Control Division.

The Cancer Detection Programs: Every Woman Counts strives to combat breast and cervical cancer on both the state and local front, by providing clinical services, quality assurance, professional education, research and surveillance, public education and outreach, and marketing campaigns throughout the year.

Program services are provided **at no cost to eligible women** and have a special focus on women 50 years and older, as well as priority ethnic populations such as African American, Asian/Pacific Islander, and American Indian.

This manual is designed to help providers follow CDS Clinical Standards when enrolling, examining, following and re-screening program eligible women. The manual is divided into sections, which address scope of the Program, patient eligibility and enrollment, provider qualifications and expectations, billing and data collection, quality assurance, clinical standards, referrals, and available resources for information and support.

Program providers have an important role. They join with CDS to assist underserved women in accessing needed services with the intent of detecting cancer early.

1.1 CDS Mission and Vision

The mission of CDS is to save lives by preventing and reducing the devastating effects of cancer for all Californians through early detection, diagnosis and treatment, with special emphasis on the underserved.

The vision of CDS is to:

- Reduce the disparities in the cancer burden.
- Ensure that all Californians have access to high quality cancer education, early detection, diagnosis and treatment.
- Have a valued and expert workforce.
- Be a leader in cancer detection and control.

- Influence healthcare systems to provide quality services.
- Program goals for breast and cervical screening are:

- To reduce mortality through breast and cervical cancer screening.
- To stimulate changes in health care and mobilize communities to enable all women to receive timely, high quality breast and cervical cancer services.

1.2 Cancer Detection Section Facts

Both state and federal dollars fund the Program. Breast and cervical cancer screening services receive funding from the Centers for Disease Control and Prevention under the Breast and Cervical Cancer Mortality Prevention Acts of 1990 (Public Law 101-354). Funding for breast cancer screening and diagnostic services is also received from 50% of revenues collected from a 2-cent tax on tobacco products, mandated by the California Breast Cancer Act of 1993.

A consortium of providers in all 58 counties offer breast cancer screening, diagnostic and treatment services. Due to funding restrictions, a limited number of providers are authorized to provide cervical as well as breast cancer screening services.

1.3 Program Covered Services

Following is a brief description of Program services. Refer to the Cancer Detection Programs: Every Woman Counts section of the Medi-Cal Manual for Program reimbursable procedures. The manual is located on the Medi-Cal website at www.medi-cal.ca.gov

BREAST CANCER SCREENING AND DIAGNOSTIC SERVICES FOR WOMEN AGE 40 AND OLDER

Clinical Breast Exam (CBE)

A clinical breast examination is reimbursable. Repeat exams are allowed for follow-up.

Screening Mammography

A screening mammogram is reimbursable.

Abnormal CBE/Mammogram Results

When a CBE or screening mammogram is abnormal, a diagnostic work-up should be initiated which may include a diagnostic mammogram and/or other diagnostic procedures.

Diagnostic Mammography

A diagnostic mammogram is reimbursable when either the CBE or the mammogram is abnormal. Repeat diagnostic mammograms are allowed for follow-up.

Breast Advanced Diagnostic Services

Covered breast diagnostic services may include diagnostic mammogram, ultrasound, FNA, core needle and excisional biopsies. Diagnostic services are reimbursed until a pathology diagnosis of cancer or not cancer is made. Cancer treatment is not covered by Cancer Detection Programs: Every Woman Counts. The woman may be referred to the Breast and Cervical Cancer Treatment Program for assistance with cancer treatment costs (see page 7-1).

CERVICAL CANCER SCREENING AND DIAGNOSTIC SERVICES FOR WOMEN AGE 25 AND OLDER (For providers authorized to provide cervical services for the Program)**Pelvic Exam**

A woman is eligible for a pelvic exam if she has had:

- No hysterectomy.
- Supracervical hysterectomy.
- Total hysterectomy due to cervical cancer.
- Hysterectomy status unknown.
- Hysterectomy cause unknown.

A woman is not eligible for a pelvic exam if she had a total hysterectomy for reasons other than cervical cancer.

Pap Smear

- Annually until the woman has had three consecutive normal Pap smears.
- After three annual consecutive normal Pap smears, the woman is to be screened once every three years or at the provider's discretion. (Refer to CDS Clinical Standards, Section 4).
- Vaginal cuff Pap smears are covered for women who have no cervix due to cervical cancer.
- Repeat Pap smears are allowed for follow-up.

Colposcopy

- For abnormal Pap smears or visual abnormalities, four biopsies, one of which is an Endocervical Curettage (ECC), can be conducted. An ECC must be billed as a biopsy.
- Diagnostic services are reimbursed until a pathology diagnosis of CIN II or III, HSIL or a diagnosis of cervical cancer is made. Treatments for these diagnoses are not covered by Cancer Detection Programs: Every Woman Counts. The woman may be referred to the Breast and Cervical Cancer Treatment Program for assistance with cancer treatment costs (see page 7-1).

2 SECTION TWO: PROVIDER PARTICIPATION

As a condition of provider participation in the Cancer Detection Programs: Every Woman Counts, primary care providers (PCP) must be invited to participate in the Program by the regional cancer detection partnerships, must be a Medi-Cal provider in good standing and sign a provider enrollment agreement. All Program providers are authorized to perform breast reimbursed services. A limited number of providers will be authorized to offer Program reimbursed cervical services. Provider eligibility requirements for the Program are subject to change at the discretion of the Cancer Detection Section.

All providers must agree not to bill eligible women for Program covered services and accept Medi-Cal reimbursement rates as payment in full. All Program services must be in compliance with all applicable federal, state, and local laws, and regulations, and delivered within accepted professional standards and principles.

All providers of the Program must have training that is appropriate to their practice and regularly update their clinical skills. The Department of Health Services has developed continuing education courses that are available to providers. Providers are encouraged to take advantage of these training opportunities. Contact your partnership for further information.

Providers must use a laboratory which is licensed by the Department of Health Services Laboratory Field Services or is Clinical Laboratory Improvement Act (CLIA) certified. Cervical cytology interpretation must be reported using the Bethesda System (either TBS II or Bethesda 2001 version).

The provider must use a radiology facility that has a current California license and a federal Food and Drug Administration certificate. Mammography interpretation must be reported according to Mammography Quality Standard Act (MQSA) requirements.

Within the Program there is a distinction between the roles and responsibilities for the primary care provider and the referral provider. The primary care provider (PCP) is enrolled in Cancer Detection Programs: Every Woman Counts through one of the regional cancer detection partnerships. The enrollment is based on the need to complete service networks in a geographic area or to improve access to care for priority populations. Referral providers receive referrals from program PCPs to render screening or diagnostic services. They may be any Medi-Cal provider in good standing. Referral providers do not enroll in Cancer Detection Programs: Every Woman Counts or sign a provider enrollment agreement.

2.1 Primary Care Provider Qualifications

The PCP must meet the following qualifications:

- Be an established provider of outpatient clinical services in good standing with Medi-Cal.
- Have web-based access to Medi-Cal with a valid Medi-Cal provider number and PIN (ID number), to access the patient enrollment and data submission application on the Internet.
- Prior to providing services, receive orientation from the partnership's clinical staff and the Electronic Data Systems' (EDS) field representative to program requirements, submission of data, and submission of hard copy or electronic claims. The EDS Rep can be accessed via the Telephone Service Center (TSC) 800-541-5555 number.

2.2 Primary Care Provider Roles and Responsibilities

The PCP must ensure that:

- Women receive appropriate breast and cervical cancer screening.
- Women will be reminded to return for routine screening.
- Women will be tracked and followed to final diagnosis.
- All data are entered on each woman served per CDS policy.

Tracking and Follow-up

The Center for Disease Control and Prevention (CDC), explains, "Tracking entails the use of a data system to monitor a woman's receipt of screening/rescreening, diagnostic, and treatment procedures. Follow-up refers to the provision of appropriate and timely clinical services following an abnormal test result and/or diagnosis of cancer."

Tracking and follow-up are important components of early detection services for breast and cervical cancer. Tracking, follow-up and rescreening have resulted in decreased mortality. Appropriate tracking and follow-up activities ensure that women return for annual rescreenings and receive diagnostic evaluation in a timely manner. The provider must ensure that:

- Priority populations are offered appropriate screening tests in accordance with CDS Clinical Standards.
- Women are notified of normal screening results within 30 days and abnormal screening results within 10 working days.
- Women with abnormal screening results receive appropriate education and information to make informed decisions regarding their options.
- Referral for required diagnostic evaluation or treatment occurs within 10 working days once results are received.
- Women receive three documented, consecutive, normal, Pap smears, performed annually and then every three years or more often at the physician's discretion.
- Women are reminded of the need for annual rescreening consisting of clinical breast examination, mammogram and Pap smear as needed.
- Three attempts will be made to remind women of rescreening needs and need for follow-up exam before they are considered lost to follow-up. The third attempt will be by certified letter.

Case Management

Cancer Detection Programs: Every Woman Counts focuses on key components to reduce mortality from breast and cervical cancer. These components are: regular and routine screening, timely diagnosis, and timely initiation of treatment when cancer is diagnosed. Lives can be saved only if patients who need services are systematically identified, referred, and given access to recommended health care services.

Case management is a key office system that ensures patients receive timely services. Case management establishes and sustains systems of clinic and support services for patients, identifies patients needing services, and refers and monitors recommended service use. Assigning tasks associated with case management as specific staff responsibilities enhances the success of this key office system. Cancer Detection Programs: Every Woman Counts defines seven key elements of case management:

Identification – Systematically determine through the use of tracking and follow-up systems, all patients with rescreening, diagnostic, and treatment needs.

- Identify regularly who needs to return for annual rescreening.
- Identify who has abnormal breast or cervical cancer screening findings and needs diagnostic studies.

- Identify who has been diagnosed with breast or cervical cancer.

Assessment – Determine the factors that may keep each patient from receiving recommended services.

- Assess each patient's practical, cultural, and educational barriers to care such as, transportation, childcare, language, fears, myths, lack of knowledge or misunderstanding about procedures.

Planning – Discuss with the patient possible solutions to barriers identified in the assessment, suggest supportive services, and document the plan.

- Explain the resources available and how to access them.

Coordination – Assist the patient to receive the recommended healthcare.

- Check whether follow-up or annual screening appointments were made and services received.

Monitoring – Re-assess the patient's needs/ability to adhere to recommended services as the diagnostic work-up continues.

- Assess for new information or support service needs as the diagnostic cycle evolves.

Resource development – Locate or negotiate for community resources that will improve access or utilization of healthcare services.

- When necessary, establish agreements to obtain screening, diagnostic, treatment, or support services.
- Ensure clinic staff is aware of community resources.
- Organize often-used support services information into an easily accessible form for clinic staff use.

Evaluation – Assess patient satisfaction and access to services received.

- Compare own practice outcome trends.

Quality Assurance

CDS has a multifaceted quality improvement program designed to continually enhance the early detection of cancer throughout California. Through data collection and evaluation, CDS identifies areas needing assistance as well as best practices by the PCPs enrolled in the Program. The PCP participates in the areas of quality improvement within the Program through periodic site reviews, chart abstractions, and data collection.

Site Reviews

Provider site reviews are conducted periodically to assess the provider's success in creating and maintaining systems to enhance screening, follow-up and rescreening of women enrolled in the Program. Site reviews performed by the

Partnership Clinical Coordinator are scheduled in advance. The provider is expected to assemble documents related to the Program and the Clinical Standards, as well as to have available the medical records for enrolled women.

At the time of the site review, technical assistance is provided by the Partnership Clinical Coordinator. This is followed by a post-review letter describing any areas needing improvement. Follow-up may be conducted to review success in instituting the recommended improvements. If CDS or the Regional Cancer Detection Partnership Clinical Coordinator determines a provider has consistently not met the Program Clinical Standards, the provider may be given a limited time to comply with the standards before being considered for disenrollment from the Program.

Aggregate data obtained during site reviews are used by Cancer Detection Partnerships and CDS for Continuous Quality Improvement (CQI) Projects. Feedback from the site reviews is used to further enhance the systems in place at various provider sites in the region.

Chart Abstractions

Periodically, Program or contract staff may require access to office records related to Program patients for quality purposes. CDS reserves the right to abstract data for Program implementation, research needs, or to correct missing data elements required for Program funding documentation.

2.3 Primary Care Provider Responsibilities for Data Collection Requirements and Reporting

Minimum Data Elements

Minimum Data Elements (MDEs) are a set of standardized data elements developed to ensure that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, tracking and follow-up, and treatment information are collected on women screened and/or diagnosed with National Breast and Cervical Cancer Early Detection Program (NBCCEDP) funds. These are the data items that are minimally necessary for NBCCEDP-sponsored Programs and CDC to monitor clinical outcomes. MDEs are incorporated into CDS' clinical standards and woven into all tenets of Cancer Detection Programs: Every Woman Counts. MDEs are collected for each woman served in the program and are converted into a standardized format. These MDEs are collected via Cancer Detection Programs: Every Woman Counts Web based online breast/cervical screening and follow-up forms.

As explained, Web based data submission for PCPs is required for Cancer Detection Programs: Every Woman Counts. The provider will report data as

mandated by CDS, using online breast/cervical screening and follow-up forms. These forms collect data on screening, timely follow-up for abnormal screening results, diagnostic procedures, outcomes, final diagnosis, treatment disposition (if warranted), and rescreening information. This data is used for program quality improvement, is submitted to Program funders, and is used to determine CDS' ability to continue funding services. CDS evaluates the data for completeness and correlation with Program Standards (see Section 4). Feedback and/or technical assistance through the partnership clinical staff will be provided as needed. Guidelines for completing the data forms are available in the Cancer Detection Programs: Every Woman Counts Step-By-Step Provider User Guide. This guide is available at: (www.medi-cal.ca.gov). Additional assistance in completing the data forms can be obtained by calling the POS/Internet Help Desk/TSC at (800) 541-5555.

CDS Data Reports

CDS staff will also send data reports to individual providers on their status with submitted data completion. These reports are sent confidentially to an assigned provider staff member who has been identified to receive personal health information on patients with missing data or unclear outcomes. These reports should be taken seriously as data are an intricate and vital part of Program funding.

Provider Responsibilities for Data Collection

All CDS PCPs are required to be enrolled in the Program and have on file a current/signed Provider Enrollment Agreement (PEA). This agreement means that the PCP will follow CDS Program Clinical Standards and provide accurate data for each woman served with Program funds in a timely fashion. CDS retains the right to require providers to take part in remedial training to maintain their status as a Program PCP when providers fail to adhere to Program requirements.

Provider Warning Process for Data Deficiencies

The Cancer Detection Section (CDS) strives to assure that all women receive appropriate and timely screening services and follow-up. To assist in this process, CDS continually monitors enrolled patients to assess data submitted per program requirements. Providers who are not meeting program requirements will be informed in writing via certified mail. It is the provider's responsibility to provide CDS with a current address. Enrolled providers are expected to report address changes to CDS via Partnership clinical staff.

CDS Data Reports

CDS furnishes reports to providers that are at risk of being out of compliance with data requirements. Reports are also provided to the Regional Cancer Detection Partnerships. Partnerships are available to provide technical assistance to providers via formal CDS Site Reviews, office assessment of systems, and additional support from sources such as Electronic Data Systems (EDS), and classes. Web-based resources may also be made available.

Provider Warnings

A provider that does not meet CDS data requirements will be given a written warning. The provider must submit all complete and accurate data within 60-days or must submit a correction plan that includes a summary of the problem and the actions to be taken to solve the problem. Providers that have received a warning and are choosing the option of the correction plan are requested to submit their plan to CDS at the earliest possible date within the 60-day time frame, in order for interventions to begin as soon as possible. If appropriate, a provider that has submitted a correction plan may be provided technical assistance and/or training from CDS.

Provider Disenrollment

Failure to respond to CDS with either the submission of data or a correction plan at the end of 60-days shall result in automatic disenrollment from the program. Providers that receive a warning and technical assistance/training, and then continue to fail to submit data, will be automatically disenrolled. Disenrolled providers that may want to reenter the program at a later date must satisfactorily demonstrate ability to meet all program requirements.

Appeal Process

Any provider that chooses to appeal disenrollment must file a written appeal that includes:

1. The issue(s) in the dispute
2. The legal authority or other basis for the appellant's position
3. The remedy sought.

Appeals that do not include all of these areas shall be rejected. Appeals may be mailed or faxed to:

Donald O. Lyman, M.D., Chief
Division of Chronic Disease and Injury Control
California Department of Health Services
MS 7200
P.O. Box 997413
Sacramento, CA 95899-7413
Fax (916) 449-5707

Health Insurance Portability and Accountability Act Responsibilities

As a health plan, Cancer Detection Section is required to protect patient information and inform the patients of their rights under HIPAA. To do this, each patient who enrolls in the Program will be given a copy of a Notice of Privacy Practices (NPP) describing how their medical information may be used or disclosed and how they may access their protected health information. Primary Care Providers enrolled in Cancer Detection Programs: Every Woman Counts have responsibilities related to providing the CDS NPP to enrolled patients. Specific information regarding these responsibilities is explained during your program orientation. Additional information can be obtained at: www.medi-cal.ca.gov

Leaving the Program

If the primary care provider decides he/she no longer wishes to continue with the Program, the provider may choose to voluntarily disenroll. The provider must send a letter to their regional partnership requesting disenrollment.

CDS may disenroll a provider from the Program if the provider is no longer in good standing with Medi-Cal, no longer has an active Medi-Cal number, or fails to maintain Program case management, Program Clinical Standards and data collection requirements. The provider will be notified by letter from CDS if these circumstances occur.

A disenrolling provider is expected to assure that patients enrolled in the Program receive continued care. Disenrolled providers are required to refer enrolled women to another Program PCP. For assistance, call the State Consumer 800 number (800) 511-2300 and identify yourself as a provider needing a referral for a patient.

Even after leaving the Program, PCPs are still required to submit data for screening and follow-up services provided during the period of time the provider was enrolled.

2.4 Referral Provider Role and Responsibilities

Referral providers include radiologists, surgeons, pathologists, anesthesiologists, mammography facilities, and hospitals. Referral providers must:

- Be a Medi-Cal provider in good standing.
- Accept women referred by the Primary Care Provider.

- Provide services within the scope of the Program.
- Report screening and diagnostic findings to the Primary Care Provider
- Bill, using the recipient ID number given them by the Primary Care Provider.
- Accept Medi-Cal reimbursement as payment in full.

3 SECTION THREE: PATIENT ELIGIBILITY

Women must meet the following age, residency and financial criteria to be eligible for enrollment in the Program:

3.1 Age Criteria

Women who meet the financial guidelines are eligible for the following reimbursed services:

- Women 40 and older are eligible for breast and cervical cancer screening and diagnostic procedures.
- Women 25 and older are eligible for cervical cancer screening and follow-up.

3.2 Residency Criteria

- Women must have a California address to be eligible for the Program.

3.3 Financial Criteria

Self-reported financial eligibility must be met in order to receive services:

- The woman's household income is at or below 200 percent of the Federal poverty level. These guidelines are adjusted annually April 1st and are published at www.medi-cal.ca.gov. Guidelines can also be found at <http://aspe.hhs.gov/poverty.htm>
- The woman must either not have any other public or private source of medical insurance coverage for screening and follow-up services, or not able to afford unmet deductibles, co-pays, or share of cost.

The Cancer Detection Programs: Every Woman Counts is the payer of last resort. All other possible third party payers including private insurance, Medicare, Medi-Cal and Family Planning-Family PACT (Planning, Access, Care and Treatment), must be exhausted prior to billing the Program.

Patients who are covered under Medi-Cal at the time of enrollment are ineligible for Program services. Exceptions are made if the client is receiving emergency Medi-Cal, prenatal Medi-Cal, or has a share of cost, which they are unable to meet.

Medicare Part B reimburses for a mammogram every year for women 65 years of age and older. Cancer Detection Programs: Every Woman Counts funds may pay for services to women not enrolled in Medicare Part B coverage. In addition, Medicare reimburses for a Pap smear every three years or at provider discretion. Program funds do not reimburse for alternate year cervical cancer screening coverage if the woman is eligible for Medicare Part B.

The Family PACT Program and Cancer Detection Programs: Every Woman Counts have the same financial requirements for participation. Women who do not qualify for the Family PACT Program may be eligible for Cancer Detection Programs: Every Woman Counts services if they meet Program financial, residential and age eligibility requirements. Family PACT clients who meet Cancer Detection Programs: Every Woman Counts eligibility requirements may utilize the Program for breast and cervical services not covered under Family PACT. However, Cancer Detection Programs: Every Woman Counts is the payer of last resort, therefore, all Family PACT covered services must first be exhausted prior to utilizing CDS Program services funding.

Women with abnormal screening mammograms through Family PACT or other providers may be referred to CDS providers for continued care. When a patient comes to you for continued care after receiving screening services from another provider, and the patient meets the Program eligibility requirements, you may enroll the patient into the Program. You may provide screening and/or follow-up services as the clinician determines is appropriate. As a PCP enrolled in the Program, you may accept the examination and testing done by another provider or repeat the exam and/or test as you deem appropriate. Women may not be enrolled in Cancer Detection Programs: Every Woman Counts solely for the purpose of receiving case management services. The patient must be in need of a clinical service not covered by another program.

For any woman that crosses over from Family PACT into Cancer Detection Programs: Every Woman Counts for breast or cervical services, the provider must submit both Family-PACT screening outcomes *and* Cancer Detection Programs: Every Woman Counts data on the Web based online breast/cervical screening and follow-up forms.

3.4 Consent

All women participating in the Program must sign the form titled Consent to Take Part in Programs and Give Personal Medical Facts. This form may be downloaded from the Medi-Cal website (www.medi-cal.ca.gov) and is available in English, Spanish Chinese, Russian, Korean, and Vietnamese. The consent must be signed once every 12 months and be kept in the individual medical record.

3.5 Recipient Eligibility Form

The Recipient Eligibility Form is used to document the woman's income and eligibility data. The form is signed by both the patient and provider and is kept in the medical record. The information contained in the form is used to enroll the woman into the Program. Patient eligibility must be re-certified every year. The form is available at www.medi-cal.ca.gov

3.6 Online Recipient Information Form

Using the information obtained in the Recipient Eligibility Form, the provider enrolls the patient online by accessing the Medi-Cal website. When the enrollment process is completed, the provider will receive a 14-character computer generated recipient ID number. This number is required on all claims from primary care and referral providers. The referral provider obtains the number from the PCP or the patient.

Detailed Program eligibility information is available in the Cancer Detection Programs: Every Woman Counts section of the Medi-Cal Manual.

Detailed enrollment procedures are available in the Cancer Detection Programs: Every Woman Counts Step-By-Step Provider User Guide available at www.Medi-Cal.ca.gov

4 SECTION FOUR: PROGRAM STANDARDS

4.1 Cancer Detection Section Clinical Standards

While certain clinical standards are procedure specific, the following standards apply to all phases of CDS programs.

Each provider shall implement a client tracking and follow up system, which ensures that:

- Records of all contacts with women are maintained. When contact with a client whose test results are abnormal is necessary, three attempts must be documented, the third attempt being by certified mail. (fewer attempts are acceptable if the recipient returns for appropriate follow-up care.)
- Screening services are provided to eligible women within 30 days of initial request.
- Women are notified of negative test results within 30 days of evaluation.
- Women are notified of abnormal test results within 10 working days.
- Referrals for required diagnostic evaluation and treatment occur within 10 days of the receipt of test results.
- The maximum elapsed time between initial examination and diagnosis is 60 days.
- The maximum time elapsed between a diagnosis of cancer and referral for treatment is 10 working days.
- Women are notified of results positive for cancer within three to five days.
- The maximum time elapsed between a diagnosis of cancer and initiation of treatment is 60 days.
- When cancer is diagnosed the provider must assist the women to secure a treatment source.
- Women return for annual re-screening.

4.2 Standards Specific to Breast Cancer Screening

- A complete breast cancer screening cycle begins with a Clinical Breast Exam (CBE) and minimally includes a Clinical Breast Exam (CBE) and mammography.
- Clinicians must correlate CBE and mammography findings.
- Abnormal CBE's require follow up despite negative mammography findings. Further diagnostic testing to determine the etiology of an abnormality is required.
- Mammography facilities are required to post a current FDA certificate, indicating compliance with MQSA standards, including reporting of mammography results to CBE providers.
- Mammography reports utilize the MQSA reporting system, required by the FDA.
- Clinicians interpreting mammograms must correlate their findings with those of the practitioner performing the CBE.
- A "probably benign" finding shall be followed by further evaluation, radiographic or otherwise.
- "Suspicious" and "highly suggestive of malignancy" findings will be communicated to the referring clinician within 3 to 5 days.
- The clinician performing the initial CBE shall arrange (or otherwise assure arrangement of) diagnostic follow up for women needing further evaluation following the reporting of mammography results to commence in 10 days or less.

Mammography Quality Standards Act

The MQSA requires that mammography reports include the following:

- The name and address of the patient and an additional patient identifier
- The date of examination
- The name of the physician who interpreted the mammogram

- Overall final assessment of findings, classified in one of the following categories:
 - “Negative”, nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).
 - “Benign”, also a negative assessment.
 - “Probably benign”, finding(s) has a high probability of being benign.
 - “Suspicious”, finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.
 - “Highly suggestive of malignancy”, finding(s) has a high probability of being malignant.
- In cases where no final assessment category can be assigned due to incomplete work-up, “Incomplete, needs additional imaging evaluation” shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting radiologist.
- Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

4.3 Standards Specific To Cervical Cancer Screening

CDS adheres to the Centers for Disease Control (CDC) guidelines regarding Pap smear results. The CDS Expert Cervical Workgroup has defined “normal” Pap smear for cervical cancer screening purposes as those listed under “benign” on the Bethesda (1994) diagnosis list.

“Women with three documented, consecutive, normal, Pap smears, performed annually (i.e. within 10-18 months of the last Pap smear) do not receive a fourth annual Pap test (see exceptions below). Thereafter, Pap tests can be repeated every three years.”

The CDS Expert Cervical Workgroup has determined that a woman may have a fourth consecutive annual Pap smear if any of the following conditions exists:

- History of Squamous Intraepithelial Lesion (SIL), or previous epithelial abnormality.

- History of cervical dysplasia or cervical cancer, or treatment for cervical dysplasia or cervical cancer.
- History of multiple sexual partners, or relations with partners who have a history of multiple sexual partners.
- Smokes, or has a history of smoking within the past year.
- Immunosuppression.
- Sexually transmitted disease or history of sexually transmitted disease.
- Early age at first intercourse.

Reporting Pap-Smear Results

- The Bethesda system, either TBSII or Bethesda 2001, will be utilized for reporting all Pap smear results.
- Women whose Pap smear specimen is inadequate or unsatisfactory will receive a repeat Pap smear.
- Individuals with Bethesda Pap smear diagnoses categorized as abnormal shall be referred for a diagnostic work-up to include colposcopy or colposcopy directed biopsy or endocervical curettage within 10 days.

Definition Of Benign and Abnormal Pap-Smear Results

The CDS Expert Cervical Workgroup in May 2002, adopted the use of Bethesda (2001) diagnoses for cervical cancer screening as published in JAMA April 24, 2002 edition.

Benign

Negative for Intraepithelial Lesion or Malignancy

- Trichomonas Vaginalis
- Fungal organisms morphologically consistent with Candida species.
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with Actinomyces species.
- Cellular changes consistent with herpes simplex virus.
- Reactive cellular changes associated with:
 - Inflammation
 - Radiation (changes)
 - Intrauterine device (IUD)
 - Atrophy
 - Other

Abnormal

Epithelial Cell Abnormalities:

Squamous Cell

- Atypical squamous cells of undetermined significance (ASC-US)
- Atypical squamous cells of undetermined significance, cannot exclude HSIL (ASC-H)
- Low-grade squamous intraepithelial lesion (LSIL) encompassing: human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia (CIN I)
- High-grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, carcinoma in situ; cervical intraepithelial neoplasia (CIN II/CIN III)
- Squamous cell carcinoma (SCC)

Glandular Cell

- Atypical glandular cells (AGC) (specify endocervical, endometrial or not otherwise specified)
- Atypical glandular cells, favor neoplasia (specify endocervical or not otherwise specified)
- Endocervical adenocarcinoma in situ (AIS)
- Adenocarcinoma

Other (List above not comprehensive)

- Specify

5 SECTION FIVE: RESOURCES

5.1 Regional Partnerships

A network of regional cancer detection partnerships funded by CDS works with local physicians and other health care professionals, public health advocates, survivors and community leaders to meet the needs of low-income underserved women. Among the network's activities are:

- Outreach & Support for Women – The partnerships and local health care professionals work together to develop coordinated resources for women's breast and cervical care in local communities.
- Conducting public education, outreach, and awareness campaigns addressing the importance of routine screening, rescreening and good health practices which promote the early diagnosis and treatment of cancer.
- Providing community linkages to client support services for women with breast and cervical cancer such as language interpretation, counseling, childcare, and transportation.
- Advocating for low-income underserved women.

The partnerships work to make breast and cervical cancer a public health priority for their regions and to develop collaborative relationships to deliver care. Among their efforts in support of health professionals are:

- Training and continuing education
- Collaboration with other providers
- Development of local networks for medical care
- Quality improvement in clinical services
- Assisting with timely diagnostic, treatment and tracking services

The following regional partnerships act as a resource for women in each California community where low-income underserved women live:

<i>San Diego/Imperial</i>	<i>(858) 554-5564</i>	<i>Orange County</i>	<i>(714) 834-7584</i>
<i>Desert Sierra</i>	<i>(951) 697-6565 x229</i>	<i>Los Angeles</i>	<i>(323) 549-0800</i>
<i>Tri-Counties</i>	<i>(805) 681-4956</i>	<i>Central Valley</i>	<i>(559) 244-4573</i>
<i>Central Coast</i>	<i>(831) 759-6598</i>	<i>Bay Area</i>	<i>(510) 535-7386</i>
<i>Gold Country</i>	<i>(916) 556-3344</i>	<i>Northern Cal</i>	<i>(530) 345-2483</i>

5.2 Professional and Public Education

The objectives for professional education for Cancer Detection Programs: Every Woman Counts providers are:

- Enhance providers' clinical practice and communication skills to assure a high quality, comprehensive approach to breast and cervical cancer screening and diagnosis.
- Provide training opportunities for primary care providers to update knowledge and skills related to breast and cervical cancer screening.
- Offer providers information and strategies to help minimize barriers to breast and cervical screening and rescreening.

CDS has developed a professional education curriculum with three separate content modules that target primary care clinicians and provider agency staff. The modules are:

- Clinical Breast Examination: Proficiency and Risk Management
- Health Providers and Women: Partners in Communication
- Breast Cancer Review

Professional education resources may be obtained by contacting the regional partnership.

5.3 Quality Assurance Project (QAP)

The Quality Assurance Project (QAP) is a collaborative effort between the San Diego State University, Graduate School of Public Health and CDS. The goal of the QAP is to improve breast and cervical cancer screening for California women. The QAP website is designed to serve as a resource for primary care clinicians. It provides program information related to the quality assurance project, the Breast Diagnostic Algorithms, and educational materials. The web address is <http://qap.sdsu.edu>

5.4 Northern California Cancer Center (NCCC) 800 Number

The NCCC 800 number serves as a resource for women eligible for the CDS Program. Providers complete and periodically update a survey for NCCC. This survey is used by NCCC to maintain a current database of enrolled Primary Care Providers. This database is used to provide women with names and addresses of providers in their area. The NCCC assists by educating women on program eligibility and providing names of local participating Primary Care Providers.

Women who need services should call the Consumer Hot-line at (800) 511-2300. This service is available Monday through Friday, from 9 a.m. to 7 p.m. Operators are available in English, Spanish, Cantonese, Mandarin, Vietnamese, and Korean.

5.5 Health Access Program (HAP)

Electronic Data Systems (EDS) processes claims for services rendered to patients in the Cancer Detection Programs: Every Woman Counts. Within in EDS is The Telephone Service Center (TSC). The TSC assists providers with billing questions, claim submissions, and other inquiries related to billing. Field representatives are available for on-site training and workshops at no cost to the provider. To contact the TSC call (800) 541-5555. The EDS representative name and phone number for each area is listed in the Cancer Detection Programs: Every Woman Counts Step-By-Step Provider User Guide.

5.6 Point of Service/Internet Help Desk

The Point of Service/Internet Help desk assists providers with access to data forms and other Internet questions. The Help Desk/TSC can be reached at (800) 541-5555.

PARTNERSHIPS

Region	Name	Counties
1	Partners for Cancer Prevention (858) 554-5564	San Diego, Imperial
2	Orange County Cancer Detection Partnership (714) 834-7584	Orange
3	Desert Sierra Partnership (951) 697-6565 X 229	Riverside, San Bernardino, Inyo
4	Partnered for Progress (323) 549-0800	Los Angeles
5	Tri-Counties Regional Partnership (805) 681-4956	Ventura, Santa Barbara, San Luis Obispo
6	Women's Health Partnership (559) 244-4573	Fresno, Kern, Kings, Madera, Mariposa, Merced, Stanislaus, Tulare, Tuolumne
7	SUCCESS Program (831) 759-6598	Monterey, San Benito, Santa Clara, Santa Cruz
8	Bay Area Breast and Cervical Health Collaborative (510) 535-7386	Alameda, Contra Costa, Marin, San Francisco, Dan Mateo, Solano
9	Gold Country Region (916) 556-3344	Alpine, Amador, Calaveras, El Dorado, Mono, Nevada, Placer, Sacramento, San Joaquin, Sierra, Sutter, Yolo, Yuba
10	Northern California Breast and Cervical Cancer Partnership (530) 345-2483	Butte, Colusa, Del Norte, Glenn, Humboldt, Lake, Lassen, Mendocino, Modoc, Napa, Plumas, Shasta, Siskiyou, Sonoma, Tehama, Trinity

6 SECTION SIX: BILLING

Cancer Detection Programs: Every Woman Counts uses the Medi-Cal process for claims submission. Services can be billed electronically or by hard copy. However, Primary Care Providers must have Internet access to obtain the recipient ID number required on each claim.

Primary Care Providers are responsible for managing patient services which are, screening, follow-up, and rescreening, as well as supplying clinical information on the Online Breast/Cervical Cancer and follow-up Forms. The Primary Care Provider will be reimbursed a case management fee after submission of the online form.

Detailed Program claims reimbursement information is available in the Cancer Detection Programs: Every Woman Counts section of the Medi-Cal Manual.

7 SECTION SEVEN: REFERRALS TO TREATMENT

The Breast and Cervical Cancer Treatment Program (BCCTP) offers treatment through the Medi-Cal Program for women and men with breast cancer or women with cervical cancer.

The Internet-based patient application is submitted online by Cancer Detection Programs: Every Woman Counts primary care providers and Family Planning-Family PACT (Planning, Access, Care and Treatment) providers. DHS determines program eligibility. For more information contact the BCCTP Eligibility Specialist at the toll-free number (800) 824-0088. References to the BCCTP can be found in the Medi-Cal Manual and at www.medi-cal.ca.gov

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